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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,751	10/06/2003	Andrea Pahmeier	2923-570	6589
6449	7590	06/16/2005	EXAMINER	
ROTHWELL, FIGG, ERNST & MANBECK, P.C. 1425 K STREET, N.W. SUITE 800 WASHINGTON, DC 20005			FUBARA, BLESSING M	
			ART UNIT	PAPER NUMBER
			1618	

DATE MAILED: 06/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/678,751	Applicant(s) PAHMEIER ET AL.	
	Examiner Blessing M. Fubara	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 51-113 is/are pending in the application.
- 4a) Of the above claim(s) 63-76, 85-88 and 91-113 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 51-62, 77-84, 89 and 90 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

Handwritten marks and signature

DETAILED ACTION

Examiner acknowledges receipt of amendment and response to restriction/election requirement filed 03/14/05.

Election/Restrictions

1. Applicants' election with traverse of Group I in the reply filed on 03/14/05 is acknowledged. The traversal is on the ground(s) that Examiner had not indicated that burden exists from examination of all the claims. This is not found persuasive because the search for method of culturing cells may not be the search for repairing cartilage or bone defect. The method for replacing microcapillary in a patient is not the same as the method for providing filler material and the searches may not be same. While applicants elected sheet as the form of the medical device, the search is extended to hollow article. Claims 51-113 are pending. Claims 51-62, 77-84, 89 and 90 are considered and claims 63-76, 85-88 and 91-113 are withdrawn from consideration as non-elected claims.

The requirement is still deemed proper and is therefore made FINAL.

Priority

2. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in Germany on 04/06/2001. It is noted, however, that applicant has not filed a certified copy of the DE application as required by 35 U.S.C. 119(b). It is also noted that application number PCT/EP02/03798 is published in German and there is no translation of that document.

3. Applicant cannot rely upon the foreign priority papers to overcome a rejection over an intervening because a translation of said papers has not been made of record in accordance with 37 CFR 1.55. See MPEP § 201.15.

Information Disclosure Statement

4. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the examiner on form PTO-892 has cited the references, they have not been considered.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 51-55 are rejected under 35 U.S.C. 102(b) as being anticipated by Thompson (US 5,531,735).

Thompson discloses medical devices fabricated from amine functionalized polymers such as chitosan and alginic acid (abstract; column 4, lines 16-19), the matrix material may be porous or non-porous (column 5, line 52), lactic acid or glycolic acid are examples of the acid resented in the matrix (column 5, lines 16-19). The device is formulated as "cylindrical shaped devices having circular cross sections, but also devices having different cross sections as long as such articles have a hollow passageway which distinguishes a tube from a rod" (column 8, lines 3-7). Claim 51 is a product claim and it is not critical how the product is formed. Thompson meets the limitations of the claims.

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7. Claims 77-83 are rejected under 35 U.S.C. 102(b) as being anticipated by Li (US 6,090,996).

Li discloses an implant comprising porous matrix sheet that is made of biocompatible and bioresorbable biopolymeric material (abstract; column 1, lines 16-19 and 30-32), the matrix sheet comprises collagen and molecules such as chitosan, growth factors, polynucleotides and combinations thereof (column 4, lines 22-29). Lactic acid is used in the formation of the collagen fibers (column 7, lines 12 and 13). Li meets the limitations of the claims.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

9. Claims 51-62, 77-84, 89 and 90 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakker et al. (US 5,508,036).

Bakker discloses a medical device that is a composite of first and second layers, the first and second layers comprising biodegradable or bioerodable polymers and these polymers that make up the first and second layers may be the same or different (abstract; column 1, lines 55-63). The first layer is non-porous (column 2, lines 45-50) and the second layer is porous (column 2, lines 51-56). Polyethers, polyamides, polyurethanes and polyesters may be employed to form the first and second layers (column 3, lines 15-40); the second layer may be formed from adhesive materials, mucoadhesives, fibrin or chitosan (column 12, lines (column 12, lines 40-50). The device contains pharmaceutical agents such as proteins, nucleic acid and

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antibiotics (column 12, lines 13-16). Although, Bakker states the types of polymeric materials in column 3, lines 15-40 as polyethers, polyamides, polyurethanes and polyesters, it is noted that Bakker makes the suggestion that the first and second layers can be made from the same polymer. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare first and second layers of the medical device according to Bakker and also prepare a medical device where both layers are made from the same polymer since that configuration is suggestion by Bakker. That is the polymer listed as the polymer for the second layer can also be the polymer for the first layer and Bakker provides the suggestion and as such success is reasonably expected that the bilayer medical device made from the same material would be expected to provide the desired deliver profile.

Note: A bilayer structure is assumed for claims 56, 57 and 84 and the claims dependent therefrom.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara
Patent Examiner
Tech. Center 1600

A handwritten signature in black ink, appearing to read "mfubara", is written over the printed name "Blessing Fubara".